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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,252	06/09/2005	Dirk A Heerding	P51399	1871

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SMITHKLINE BEECHAM CORPORATION
CORPORATE INTELLECTUAL PROPERTY-US, UW2220
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EXAMINER

HAVLIN, ROBERT H

ART UNIT	PAPER NUMBER
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1626

NOTIFICATION DATE	DELIVERY MODE
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12/05/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

US_cipkop@gsk.com

Office Action Summary	Application No. 10/538,252	Applicant(s) HEERDING ET AL.	
	Examiner ROBERT HAVLIN	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 45-55 is/are pending in the application.
- 4a) Of the above claim(s) 55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 45-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/22/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims: Claims 45-55 are currently pending. Claim 55 is withdrawn for reading on the non-elected product group.

Priority: This application is a 371 of PCT/US03/39633 (12/12/2003) which claims benefit of 60/433,482 (12/13/2002).

RCE: A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/22/08 has been entered.

Response to Applicants Arguments

1. Claims 45-54 were rejected under 35 U.S.C. 103(a) as being unpatentable over **Ajito et al.** (WO 99/38849, US 6451800), in view of **Ayal-hershkovitz et al.** (WO 02/060374) and **Raeymaekers et al.** (US 4,859,684).
2. Applicant argues that Ajito teaches away from the instant invention because they are blood thinners and would be given to people to decrease platelet activity. Applicant asserts that Ajito teaches away from the claimed invention because the claimed treatment of thrombocytopenia is in fact to increase platelet activity.
3. Based upon closer examination of the Ajito et al. and Ayal-Hershkovitz et al. references and applicant's arguments, the rejections are withdrawn in favor of the following 102 rejection.

NEW CLAIM REJECTIONS

Claim Rejections - 35 USC § 102

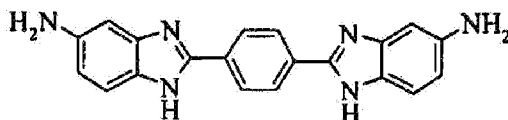
1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

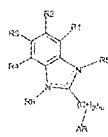
2. Claims 45, 46, 48, 50, 51, 53 and 54 are rejected under 35 U.S.C. 102(b) as being anticipated by Ayal-herskovitz et al. (WO 02/060374) and in the alternative obvious in view of Miller et al. (US 5,753,671).

Compound 17 on page 51:



is a member of the

genus of the instant claims where



(d) R1, R3, R4, R6 are H; R2 is NH₂; R5 is absent; m is 0; AR is a substituted cyclic aromatic ring (phenyl), substituted by a substituted aryl.

Miller et al teaches in claim 18 use of a similar genus of benzimidazole compounds for treating thrombocytopenia in humans. While Ayal-herskovitz appears to fully anticipate the claims, any arguable differences would be cured by the teachings of Miller and the knowledge of one of ordinary skill in the art because Miller explicitly claims the method of using the benzimidazole compounds in treating patients. Therefore, the claims are also obvious.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 46-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. While the compounds taught by Ayal-herskovitz referred to above appear to be enabled, there is no indication in the instant specification that the entire claim scope can be practiced by one of ordinary skill in the art.

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the specification coupled with information known in the art without undue experimentation (*United States v. Telectronics*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is needed is not based upon a single factor but rather is a conclusion reached by weighing many factors. These factors were outlined in *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Int. 1986) and again in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) and include the following:

Nature of Invention. The nature of the invention involves the method of using pharmaceutical agents in treating patients.

Scope of the Invention. The scope of the invention in the claims includes the treatment of thrombocytopenia in mammals with a broad genus of compounds of formula (I).

State of the Art and Level of Skill in the Art. Ayal-herskovitz demonstrates how selected benzimidazole compounds are useful for the treatment of thrombocytopenia, however, the art remains very unpredictable when the underlying structure of the pharmaceutical agents are modified. Thus, one of ordinary skill in the art could not predict or determine which compounds of Formula (I) are useful without requiring undue experimentation.

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Number of Working Examples and Guidance Provided by Applicant. The applicant provides no working examples of treating thrombocytopenia with the compounds of Formula (I).

Unpredictability of the Art and Amount of Experimentation. The art of using pharmaceuticals to prevent disease is unpredictable. In nearly every case, the skilled artisan could not predict *a priori* whether a given pharmaceutical would treat any given disease. Furthermore, there would be a huge amount of experimentation required in order to arrive at the appropriate formulation, protocol, and determination of effectiveness before the skilled artisan could claim to have treated any disease with a given pharmaceutical.

Considering the above factors, the claims are clearly not enabled for the methods of treating thrombocytopenia with the genus of compounds of Formula (I).

Conclusion

The claims are not in condition for allowance.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./
Primary Examiner, Art Unit 1626